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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/989,092	11/19/2001	Jeffrey L. Garwin	13222.00014	9289

7590 01/14/2004

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EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 01/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No.	Applicant(s)	
	09/989,092	GARWIN, JEFFREY L.	
	Examiner	Art Unit	
	RANDALL WINSTON	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on 11/03/2003

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) *1-48* is/are pending in the application.

4a) Of the above claim(s) *32-34 and 37-48* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-31,35 and 36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5/28/2003 02/25/2002
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of rejoined Groups I, II, and V in applicant's election/restriction response of 11/03/2003 is acknowledged. The traversal is based on the grounds that applicant argues that the examination of the claims of Groups III and IV, drawn to methods of prognosing a patient's response to cancer therapy employing the method of claim 1, along with examination of rejoined Groups I, III, and V would not impose a serious burden on the examiner.

Applicant argument is not found persuasive because, as Examiner explained in the Restriction Requirement (10/03/2003), Group III and IV are distinct from Group I, II, and V because Group III and IV utilize different steps to achieve its different preamble objective and/or purpose.

The restriction requirement is still deemed proper and its therefore made final.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-31 and 35-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 35 are rendered vague and indefinite for the phrase "dysplastic or carcinomic." Applicant may overcome this rejection by placing the word "either" before the phrase. (e.g. either dysplastic or carcinomic).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under 35 U.S.C. 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 5-7, 10, 14-16, 20-28, 30, 31, and 35-36 are rejected under 35 U.S.C 102(e) as being anticipated by Adair et al. (US 6,316,215).

Applicant claims a method (i.e. to determine if a sample of cells contains either dysplastic or carcinomic cells and/or to diagnose a patient for early-stage cancer and/or to detect dysplastic or carcinomic cells in a selected target tissue) comprising the steps of contacting the sample with a solution of TCPP under conditions to permit binding of TCPP to abnormal precancerous or cancerous cells, removing unbound TCPP from the sample, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity of fluorescent cells and/or by flow cytometer, the presence of TCPP

fluorescence being indicative that the sample contains either dysplastic or carcinomic cells.

Adair et al. anticipate the claimed invention (see, e.g. abstract, column 4 lines 25-67, column 12 lines 54-60) because Adair et al. teach a method of cancer screening (i.e. pre-malignant and malignant cells) comprising the steps of contacting the sample with a solution of TCPP under conditions to permit binding of TCPP to abnormal precancerous or cancerous cells, removing unbound TCPP from the sample, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity of fluorescent cells and/or by flow cytometer, the presence of TCPP fluorescence being indicative that the sample contains either dysplastic or carcinomic cells. Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-31 and 35-36 are rejected under 35 U.S.C 103(a) as being unpatentable over Adair et al.

Applicant claims a method (i.e. to determine if a sample of cells contains either dysplastic or carcinomic cells and/or to diagnose a patient for early-stage cancer and/or to detect dysplastic or carcinomic cells in a selected target tissue) comprising the steps

of contacting the sample (i.e. sample is fixed on a slide support in a liquid medium on a microscope slide) with a solution of TCPP (i.e. TCPP is pre-dissolved at a particular pH) under conditions (i.e. at a particular TCPP concentration and at a particular contact time and temperature) to permit binding of TCPP to abnormal precancerous or cancerous cells, removing unbound TCPP from the sample, contacting the sample with a detectable marker which is a fluorescent compound that binds to all cells in the sample, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity of fluorescent cells and by utilization of a fluorometric flow cytometer and determining the percentage of cells in the sample that are TCPP-fluorescent because the presence of TCPP fluorescence being indicative that the sample contains either dysplastic or carcinomic cells.

The primary reference is relied upon for the reasons discussed above. Adair et al. do not expressly teach that the cells are fixed, TCPP is pre-dissolved at a particular pH, TCPP being at a particular concentration and TCPP contacted at a particular time and temperature and the percentage of cells that are TCPP bound. However, based upon the overall beneficial teachings provided by Adiar et al., the result-effective adjustment of conventional working conditions therein (e.g., the cells are fixed, TCPP is pre-dissolved at a particular pH, TCPP being at a particular concentration and TCPP contacted at a particular time and temperature and the percentage of cells that are TCPP bound), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, the invention as a

whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 5-7, 14-16, 30,31, and 35-36 are rejected under 35 U.S.C 102 (b) as being anticipated by Cole et al. (US 5,391,547).

Applicant claims a method (i.e. to determine if a sample of cells contains either dysplastic or carcinomic cells and/or to diagnose a patient for early-stage cancer and/or to detect dysplastic or carcinomic cells in a selected target tissue) comprising the steps of contacting the sample with a solution of TCPP under conditions to permit binding of TCPP to abnormal precancerous or cancerous cells, removing unbound TCPP from the sample, detecting TCPP fluorescence in the sample by flow cytometer, the presence of TCPP fluorescence being indicative that the sample contains either dysplastic or carcinomic cells.

Cole et al. anticipate the claimed invention (see, e.g. abstract, column 3 lines 41-46, column 4 lines 40-66, column 5 lines 21-35, column 6 lines 21-44) because Cole et al. teach a method of cancer screening (i.e. pre-malignant and malignant cells) comprising the steps of contacting the sample with a solution of TCPP under conditions to permit binding of TCPP to abnormal precancerous or cancerous cells, removing

unbound TCPP from the sample, detecting TCPP fluorescence in the by flow cytometer, the presence of TCPP fluorescence being indicative that the sample contains either dysplastic or carcinomic cells. Therefore, the reference is deemed to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-31 and 35-36 are rejected under 35 US 103(a) as being unpatentable over Cole et al.

Applicant claims a method (i.e. to determine if a sample of cells contains either dysplastic or carcinomic cells and/or to diagnose a patient for early-stage cancer and/or to detect dysplastic or carcinomic cells in a selected target tissue) comprising the steps of contacting the sample (i.e. sample is fixed on a slide support in a liquid medium on a microscope slide) with a solution of TCPP (i.e. TCPP is pre-dissolved at a particular pH) under conditions (i.e. at a particular TCPP concentration and at a particular contact time and temperature) to permit binding of TCPP to abnormal precancerous or cancerous cells, removing unbound TCPP from the sample, contacting the sample with a detectable marker which is a fluorescent compound that binds to all cells in the sample, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity

of fluorescent cells and by utilization of a fluorometric flow cytometer and determining the percentage of cells in the sample that are TCPP-fluorescent because the presence of TCPP fluorescence being indicative that the sample contains either dysplastic or carcinomic cells.

The primary reference is relied upon for the reasons discussed above. Cole et al. do not expressly teach that the TCPP is pre-dissolved at a particular pH, TCPP being at a particular concentration and TCPP contacted at a particular time and temperature, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity of fluorescent cells and the percentage of cells that are TCPP bound. However, based upon the overall beneficial teachings provided by Cole et al., the result-effective adjustment of conventional working conditions therein (e.g., TCPP is pre-dissolved at a particular pH, TCPP being at a particular concentration and TCPP contacted at a particular time and temperature, detecting TCPP fluorescence in the sample by characterizing the fluorescence intensity of fluorescent cells and the percentage of cells that are TCPP bound), is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan. Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RANDALL WINSTON whose telephone number is 703-305-0404. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 703-306-3220. The fax phone number for the organization where this application or proceeding is assigned is 703-746-3110.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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Brenda Brumback
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